DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 1

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[Docket No. 2002N–0278]

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Interim final rule; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending to July 13, 2004, the comment period on the prior notice interim final rule (IFR) that appeared in the **Federal Register** of October 10, 2003 (68 FR 58974). The prior notice IFR requires the submission to FDA of prior notice of food, including animal feed, that is imported or offered for import into the United States. FDA reopened the comment period for 30 days in the **Federal Register** of April 14, 2004 (69 FR 19766), to solicit comments on the "Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes" and to ensure that those who comment on this IFR would have had the benefit of our outreach and education efforts and would have had some experience with the systems, timeframes, and data elements of the prior notice system. In response to a request from the Government of Canada, FDA is extending the comment period for an additional 60 days. Accordingly, the comment period for the prior notice rulemaking, including the comment period

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for the "Joint FDA-CBP Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes," is extended to July 13, 2004.

DATES: Submit written or electronic comments no later than July 13, 2004.

ADDRESSES: You may submit comments, identified by Docket 2002N–0278, by any of the following methods:

- Federal eRulemaking Portal: *http://www.regulations.gov.* Follow the instructions for submitting comments.
- Agency Web site: *http://www.fda.gov/dockets/ecomments.* Follow the instructions for submitting comments on the agency Web site.
- E-mail: *fdadockets@oc.fda.gov.* Include Docket No. 2002N–0278 in the subject line of your e-mail message.
- FAX: 301–827–6870.
- Mail/Hand delivery/Courier [For paper, disk, or CD-ROM submissions]: Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Instructions: All submissions received must include the agency name and Docket No. or Regulatory Information Number (RIN) for this rulemaking. All comments received will be posted without change to *http://www.fda.gov/dockets/ecomments*, including any personal information provided. For detailed instructions on submitting comments and additional information on the rulemaking process, see the "Comments" heading of the **SUPPLEMENTARY INFORMATION** section of this document.

Docket: For access to the docket to read background documents or comments received, go to *http://www.fda.gov/dockets/ecomments* and/or the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: May D. Nelson, Center for Food Safety and Applied Nutrition (HFS–24), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 301–436–1722.

SUPPLEMENTARY INFORMATION: FDA issued this rule as an IFR, with an opportunity for public comment for 75 days. Moreover, to ensure that those that comment on this IFR would have had the benefit of actual experience with the systems, timeframes, and data elements, FDA reopened the comment period for an additional 30 days on April 14, 2004 (to close on May 14, 2004). On April 29, 2004, FDA received a request from the Government of Canada to extend the comment period for an additional 60 days (Comment EXT1, 2002N–0278) (69 FR 19763). According to the Canadian government, the 30-day comment period does not allow Canada to consult adequately with its stakeholders and formally explore with FDA effective alternatives in response to FDA's request for comments. Additionally, Canada states it is concerned that its industry is not yet fully aware of the prior notice IFR's impact since during the initial period of implementation feedback to affected industries from FDA and Customs and Border Protection concerning noncompliance was minimal. The Government of Canada submitted this request with the understanding that such an extension would not interfere with the issuance of the prior notice final rule, which FDA plans to publish in March 2005. FDA intends to publish a final rule in an expeditious manner while carefully considering the comments we receive.

Comments

In response to the request from the Government of Canada, we are extending the comment period an additional 60 days to close on July 13, 2004. Accordingly, we are seeking comments on all aspects of the prior notice IFR,

including the specific questions we posed in the previous notice to reopen the comment period (see 69 FR 19763 at 19764), and the "Joint Food and Drug Administration-Customs Border Protection Plan for Increasing Integration and Assessing the Coordination of Prior Notice Timeframes" (69 FR 19765).

To be timely, interested persons must submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the prior notice IFR by July 13, 2004. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

This regulation was effective on December 12, 2003. We will address comments received during the entire reopened comment period and the previous comment period that closed on December 24, 2003, and will confirm or amend the IFR in a final rule. We, however, will not address any comments that have been previously considered during this rulemaking.

Dated: May 12, 2004

May 12, 2004.

William K. Hubbard,
Associate Commissioner for Policy and Planning.

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